REMARKS/ARGUMENTS

The foregoing amendments cancel the claims directed to murine GFRα3 and add new claims directed to human GFRα3. The new claims 98-102 are identical to claims 72, 73, 77, 81 and 85 that were previously pending in the application. The newly introduced claims are fully supported by the specification as originally filed, such as, for example, at page 3, lines 16 - 38; Example 2; and page 27, line 1 to page 29, line 14. The added claims do not contain new matter. With this Amendment, claims 98-102 are pending.

Prior to entry of the present amendment, claims 87-97 were pending in this application; these claims stand cancelled by this amendment. Added claims 98-102 recite the subject matter of previously presented claims 72, 73, 77, 81 and 85 that were rejected under 35 U.S.C. §101 as allegedly lacking utility and under 35 U.S.C. §112 first paragraph, also for the alleged lack of utility. Applicants respectfully submit that claims 98-102 recite a new and useful invention, and present the following remarks regarding the utility of the claimed invention.

Utility

Prior claims 72-73, 77, 81 and 85 were rejected under 35 U.S.C. § 101 as allegedly "not supported by either a specific and/or substantial asserted utility or a well established utility." The ultimate basis for this rejection was that the endogenous ligand of GFRα3 was not known at the time the present invention was made and, in the Examiner's view, for this very reason it did not have any "real world" utility as of the filing date. However, Applicants respectfully submit that knowledge of an endogenous ligand is not required for the use of that ligand. Applicants respectfully submit that pending claims 98-102 are supported by specific and substantial asserted utility.

The legal framework

The statutory requirement (35 U.S.C. 101) that the invention must be "useful" has been interpreted as requiring that a specific and substantial credible utility must be available as of the filing date, either as asserted in the specification or as well established in the art.

The requirement of "specific utility" means a utility specific to the claimed subject matter, as opposed to a general utility which applies to a broad or collective class of inventions. (MPEP 2107.01.) The requirement of "substantial utility" concerns a real world utility in a currently available form (Brenner v. Manson, 383 U.S. 519, 534-35, 148 USPQ 689, 695 (Fed. Cir. 1966)).

An assertion of a specific and substantial utility is considered to be credible unless the logic underlying the assertion is seriously flawed. Thus, the asserted utility is considered credible if a person of ordinary skill in the art would accept that the invention is currently available for the use asserted by the applicant as of the effective filing date.

It is sufficient to establish one patentable utility in order to meet the utility requirement of 35 U.S.C. 101.

The claimed invention

The claims pending in this application concern nucleic acid molecules encoding the GFRα3 polypeptide of SEQ ID NO: 17, vectors comprising such nucleic acid molecules, host cells comprising such vectors, and a process directed to the recombinant production of a GFRα3 polypeptide by culturing such host cells. The common feature of all claims is the use of a nucleic acid encoding a GFRα3 polypeptide of SEQ ID NO: 17, and the question is whether applicants have established at least one patentable utility for such nucleic acid.

Utility information provided in the present application

The polypeptide of SEQ ID NO: 17 is a human GFRα3 receptor. Although nucleic acids and polypepides may have different utilities, utility of a polypeptide also establishes utility for the nucleic acid encoding such polypeptide.

A human GFRα3 receptor provides treatments for peripheral nervous system diseases

The specification, in the passage bridging pages 28 and 29, provides that "[a]gents which bind to the GFRα3 molecule could be useful in the treatment of diseases or conditions involving

the peripheral nervous system," such as "peripheral neuropathies associated with diabetes, HIV, chemotherapeutic agent treatments" and neuropathic pain. In the same section "antagonists" of GFRα3 are stated to be useful "to treat chronic pain of non-neuropathic nature, such as ... that which is associated with various inflammatory states."

The asserted utilities are supported in the specification

These asserted utilities "are consistent with the data of Example 5 in which a strong expression of GFRα3 within the developing and adult sensory ganglia was observed." (page 29, lines 1-2.) Applicants note (page 29, lines 9-14) that agonists and antagonists to GFRα3 lack some side effects which may be associated with ligands which bind to GFRα1 and GFRα2 (GDNF and neurturin), stating "Thus, ligands which act via GFRα3 will be particularly useful to treat disorders of the peripheral nervous system while including fewer effects on weight loss, motor functions, or on kidney function than would ligands acting via GFRα1 or GFRα2."

Ligands (e.g., antibodies) are disclosed in the specification

According to the definition provided at page 15, lines 8-10, the term "ligand" is used to refer to a molecule which is able to bind to the extracellular α-subunit receptor of interest, or a known agonist thereof. Accordingly, the term "ligand" is not limited to the native biological ligand of a receptor. Indeed, on pages 29-33, the specification provides a detailed disclosure of anti-GFRα3 antibodies, which are clearly within the scope of "ligands" as defined for the purpose of the present invention.

Possession of the endogenous ligand is not required for a useful invention

The Examiner stated that "without knowing the native ligand of GFRα3, one of ordinary skill in the art would not reasonably know what specific "conditions" could reasonably be "treat[ed]" (page 4, lines 3-6, Paper No. 24). Applicants respectfully disagree. For example, opiate receptor ligands were used as painkillers and anesthetics in the absence of any knowledge of endorphins or enkephalins. The utility of opiate receptors and of ligands that bind opiate receptors were well-known and used long before the endogenous ligands of opiate receptors were discovered. Thus, one of ordinary skill in the art would know that possession of the GFRα3 receptor was sufficient for the practice of the claimed invention.

Application of the law

The totality of the disclosure provided in the specification reasonably conveyed to one skilled in the art at the effective filing date of this application that agents (including antibodies) which bind to GFRα3 find utility in the treatment of neuropathies associated with the peripheral nervous system, and chronic pain, whether neuropathic or non-neuropathic in nature.

The asserted utility is also "substantial," since it provides a real world utility in a currently available form.

The asserted utility is not based in any way on the discovery of putative ligands of GFRα3 that were not known in the art at the effective filing date of the present application. In view of the teaching of the specification, the knowledge of the native ligand, or the discovery of cc putative" agonists or antagonists is not required to utilize the invention for the stated purpose. Antibodies specifically binding GFRα3 could be readily generated at the filing date of this application, both based on the detailed teaching in the specification, and on general knowledge in the art. The use of such antibodies to treat the indicated conditions was well within the skill of the art at the relevant time frame. Accordingly, the stated specific utility was currently available as of the filing date, and is also "substantial."

It is emphasized that the utility should be examined in the context of the claimed invention. The claims are not directed to the identification of the native ligand, or any "putative" ligand of GFRα3, and the invention as claimed has utility without such discovery.

Finally, the logic underlying the asserted specific and substantial utility is not seriously flawed, therefore, one skilled in the art would have found the stated utility "credible" at the effective filing date of this application.

CONCLUSION

The claimed invention being supported by a specific and substantial asserted utility, Applicants believe that all claims pending in this application are in *prima facie* condition for allowance. Allowance of pending claims 98-102 is respectfully requested and an early issuance of a Notice of Allowance is respectfully solicited.

Please charge any additional fees, including any fees for extension of time, or credit overpayment to Deposit Account No. 08-1641.

Respectfully submitted,

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